

1212583

Date:

JUL 25 2012

510(k) Summary**3-1. 510(k) owner (submitter)**

- | | |
|---------------------------|---|
| 1) Name | Kuraray Noritake Dental Inc. |
| 2) Address | 1621 Sakazu, Kurashiki, Okayama 710-0801, Japan |
| 3) Contact person | Michio Takigawa
Quality Assurance Department |
| 4) Contact person in U.S. | Kiyoyuki Arikawa
KURARAY AMERICA INC.
33 Maiden Lane, 6 th Floor, New York,
NY 10038
Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676
Fax: (888)-700-5200 |

3-2. Name of Device

- | | |
|-----------------------------|--|
| 1) Trade / Proprietary name | CLEARFIL MAJESTY ES-2 |
| 2) Classification name | Tooth shade resin material
(21 CFR section 872.3690. Product code: EBF) |
| 3) Common name | Dental light-cured restorative composite |

3-3. Predicate device

- | | |
|------------------------------|---|
| 1) CLEARFIL MAJESTY Esthetic | 510(k) Number: K061860
Product Code: EBF
21 CFR Section: 872.3690
Applicant: Kuraray Noritake Dental
Inc. |
| 2) CLEARFIL MAJESTY Flow | 510(k) Number: K063593
Product Code: EBF
21 CFR Section: 872.3690
Applicant: Kuraray Noritake Dental
Inc. |

3-4. Description of device

- 1) The subject device, CLEARFIL MAJESTY ES-2, is a light-cure, radiopaque restorative material which provides accurate color matching, high polishability and excellent physical properties, making it ideal for both anterior and posterior restorations. It is formulated with optimal viscosity assuring easy handling and placement. It is packaged in traditional syringes or Pre-loaded tips (PLTs).

The lightness/ value based unique shade taking system of its Shade guide provides shade taking options for single (Classic) and dual (Premium) shade layering for highly esthetic restorations.

It is intended for the following indications:

- [1] Direct restorations for all cavity classes in anterior and posterior teeth
 - [2] Direct veneers
 - [3] Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)
 - [4] Intraoral repairs of fractured restorations
- 2) It is classified into tooth shade resin material (21 CFR section 872.3690, Product code: EBF) according to 21 CFR § 872 since it is composed of materials such as Bisphenol A diglycidylmethacrylate (Bis-GMA).
- 3) Physical and mechanical properties of the subject device are evaluated according to ISO 4049: 2009 (Dentistry - Polymer-based restorative materials). According to ISO 4049: 2009, the subject device is classified into the following:
- Type 1: Polymer-based restorative materials;
 - Class 2: materials whose setting is effected by light;
 - Group 1: materials whose use requires the energy to be applied intra-orally.

3-5. Substantial Equivalence Discussion

- 1) Intended uses

The INDICATIONS of the subject device were written up based on that of the predicate device. Therefore, the intended purposes of the subject device are substantially the same as that of the predicate one.

- 2) Chemical ingredients / Safety

All chemical ingredients of the subject device are equivalent to those of the predicate devices, CLEARFIL MAJESTY Esthetic and CLEARFIL MAJESTY Flow.

Regarding the predicate devices, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US.

- 3) Effectiveness / Performance

The subject device complies with all requirements of ISO 4049: 2009 as polymer-based restorative materials.

Regarding the comparison with the predicate device according to ISO 4049: 2009, the subject device and the predicate device comply with ISO 4049: 2009 indicating that the subject device is substantially equivalent in safety and effectiveness to the predicate device.

3-6. Biocompatibility

All the chemical ingredients of the subject device are equivalent to those of the predicate devices, CLEARFIL MAJESTY Esthetic and CLEARFIL MAJESTY Flow.

Regarding the predicate devices, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US.

Accordingly, it was considered that the subject device was substantially equivalent in safety to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Kuraray Noritake Dental, Incorporated
C/O Mr. Kiyoyuki Arikawa
General Manger
Kuraray America, Incorporated
33 Maiden Lane, 6th Floor
New York, New York 10038

JUL 25 2012

Re: K121583
Trade/Device Name: Clearfil Majesty ES-2
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: May 28, 2012
Received: May 30, 2012

Dear Mr. Arikawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

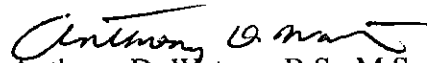
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 12 1583

Device Name: CLEARFIL MAJESTY ES-2

Indications for Use:

- 1) Direct restorations for all cavity classes in anterior and posterior teeth
- 2) Direct veneers
- 3) Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)
- 4) Intraoral repairs of fractured restorations

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use N/A
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Turner
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 12 1583